

## **Navajo Nation Human Research Review Board Institutional Review Board Meeting Agenda**

DATE: October 15, 2019, TIME: 9:00 AM

PLACE: NODH Conference Room, Window Rock, AZ

### **MEMBERS:**

Beverly Becenti-Pigman, Chairperson - Community  
Dr. David Begay, Ph.D. - Scientific Education  
Dr. Nanibaa' Garrison, Ph.D. - Genetics, Bio-Ethics  
Dr. Sonya Shin, MD – Medicine  
Delvin Yazzie, MPH - Epidemiology  
Dr. Rebecca Izzo-Manymules, PhD – Education  
Ursula Knoki-Wilson, MSN, MPH – Nursing  
Dr. Calvin White, Ph.D. - Scientific Education

### **OLD BUSINESS:**

I. Meeting Call to Order:

II. Roll Call:

- Invocation:

- Introductions:

III. Review and Approval of Agenda:

IV. Review and Acceptance of September 17 Meeting Minutes:

### **NEW BUSINESS:**

V. Quarterly Reports:

VI. Serious Adverse Events (SAEs):

VII. New Presentations:

VIII. Returning Presentations:

IX. Noon Hour Discussion:

X. Abstracts Review:

XI. Announcement / Adjournment:

**Navajo Nation Human Research Review Board  
IRB 10/15/2019 Meeting Agenda**

**SERIOUS ADVERSE EVENT(S)**

1. NNR-02.094 PI: Knowler, William MD  
**Action for Health in Diabetes Look AHEAD**
2. NNR-02.110 PI: Knowler, William MD  
**Diabetes Prevention Program Outcomes Study (DPPOS)**
3. NNR-16.264 PI: Reid, Raymond MD  
**Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months, Part II: 18 Months**

**NEW PRESENTATION(S)**

1. NNR-19.361T PI: James, Perry R. M.A.  
**Navajo Sweat House Leadership: Acquiring Traditional Navajo Leadership for Restoring Identity in our Forgotten World**  
Reason on New Title  
Description: Request Review and Approval of New Study
2. NNR-19.362T PI: Hafford, Carol PhD  
**Survey of Head Start Grantees on Training and Technical Assistance**  
Reason on New Title  
Description: Request Review and Acceptance of New Study

**RETURNING PRESENTATION(S)**

1. NNR-02.106 PI: Dabelea, Dana MD  
**SEARCH for Diabetes in Youth Study**  
Reason on Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering June 18 - September 18, 2019 period
2. NNR-02.110 PI: Knowler, William MD  
**Diabetes Prevention Program Outcomes Study (DPPOS)**  
Reason on Quarterly Review  
Description: Request Review and Acceptance and Approval of Quarterly Report covering April 1 - June 30, 2019 period
3. NNR-05.175 PI: Mohs, Kimberly MD  
**Navajo Area Indian Health Services - Cardiovascular Risk Reduction Demonstration Project**  
Reason on Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report ending October 2019 period
4. NNR-17.266 PI: Ingram, Jani C Ph.D.  
**Mutton Consumption Survey**  
Reason on Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering May 21 - August 21, 2019 period
5. NNR-19.334 PI: McCabe, Kendrick N BA  
**Reclaiming Traditional Names to Promote Din'e (Navajo) Language and Culture**  
Reason on Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering May 21, 2019 - September 21, 2019 period

6. NNR-19.342 PI: Uechi, Manami MD  
**Measuring the impact of the Navajo Fruit and Vegetable Perception (FVRx) Program on Childhood Obesity in an American Indian Community: A mixed Methods Study in Navajo Nation**  
**Reason on** Quarterly Review  
 Description: Request Review and Acceptance of Quarterly Report covering June 18 - September 18, 2019 period
7. NNR-15.222 PI: Huyser, Kimberly R. Ph.D.  
**The American Indian Reservation as a source of Risk and Resilience against Psychological Distress: An Analysis of Two American Indian Tribes**  
**Reason on** Quarterly Review  
 Description: Request Acceptance of Quarterly Reports covering 1) April 1 - June 30, 2019, 2) July 1 - September 2019 periods  
**Reason on** Annual Report  
 Description: Request Acceptance and Approval of Annual Report covering October 19, 2018 - October 19, 2019 period  
**Reason on** Final Report  
 Description: Request Acceptance and Approval of Final Report and to Request to Close Out Study
8. NNR-15.225 PI: Baudean, Shelly  
**Achieving Success by Promoting Readiness for Education and Employment**  
**Reason on** Final Report  
 Description: Request Acceptance and Approval of Final Report covering October 2015 - October 2019 period
9. NNR-11.346 PI: Reid, Raymond MD  
**Together on Diabetes Study: Evaluation of a pilot Diabetes Prevention and Management Program for American Indian Youth.**  
**Reason on** Continuation Request  
 Description: Request Acceptance and Approval of Continuation Request covering December 21, 2019 - December 21, 2020 Period.
10. NNR-16.264 PI: Reid, Raymond MD  
**Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months, Part II: 18 Months**  
**Reason on** Continuation Request  
 Description: Request Acceptance and Approval of Continuation Request Part I covering December 20, 2019 - December 20, 2020 period
11. NNR-02.111 PI: Reid, Raymond MD  
**Effects of Maternal Influenza Vaccination on Respiratory Disease among Infants**  
**Reason on** Annual Report  
 Description: Request Acceptance and Approval of Annual Report covering August 20, 2018 - August 20, 2019 period
12. NNR-05.165 PI: Reid, Raymond MD  
**Long Term Impact of the Pneumococcal Conjugate Vaccine on Pneumococcal Nasopharyngeal Colonization and Immune Correlates for Disease Protection**  
**Reason on** Annual Report  
 Description: Request Acceptance and Approval of Annual Report covering September 6, 2018 - September 6, 2019 period
13. NNR-07.216 PI: Reid, Raymond MD  
**Haemophilus Influenzae among southwestern American Indian Children**  
**Reason on** Annual Report  
 Description: Request Acceptance and Approval of Annual Report covering September 18, 2018 - September 18, 2019 period
14. NNR-04.151 PI: Hammitt, Laura MD  
**A Phase 3 Study of MEDI-524 (Numax®), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease Among Navajo and White Mountain Apache Infants in the Southwestern United**  
**Reason on** Annual Report  
 Description: Request Acceptance and Approval of Annual Report covering September 21, 2018 - September 21, 2019 period

15. NNR-18.304 PI: Howley, Caitlin MS **TABLED – used item from September 17 Meeting packet**  
**Indigenous Math Circles Community (IMACC) Evaluation**  
**Reason on** Annual Report  
Description: Request Acceptance and Approval of Annual Report covering June 19, 2018 - June 18, 2019 period
16. NNR-13.166 PI: Hilgert, Uwe PhD.  
**Cultivating Diverse Talent in STEM (CDTIS)**  
**Reason on** Quarterly Review  
Description: Request Review and Acceptance of Quarterly Reports: 1) March 17 - June 17, 2019, 2) June 17, - September 17, 2019  
**Reason on** Continuation Request  
Description: Request Acceptance and Approval of Continuation Request covering December 17, 2019 - December 17, 2020 period
17. NNR-15.223 PI: Richards, Jennifer MPH  
**Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.**  
**Reason on** Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2019 period  
**Reason on** Continuation Request  
Description: Request Acceptance and Approval of Continuation Request covering December 15, 2019 - December 15, 2020 period
18. NNR-18.322 PI: Werito, Vincent Ph.D.  
**Developing Community Partnerships Through Research to Define Community Well-Being from a Dine' Centered Perspective with Three (Dine') Navajo Communities in New Mexico**  
**Reason on** Annual Report  
Description: Request Acceptance and Approval of Annual Report covering October 16, 2018 - October 16, 2019 period  
**Reason on** Continuation Request  
Description: Request Acceptance and Approval of Continuation Request covering October 16, 2019 - October 16, 2020 period
19. NNR-04.145 PI: Lewis, Johnnye L. Ph.D.  
**Dine Network for Environmental Health Project (DiNEH)**  
**Reason on** Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering April 21 - July 20, 2019 period  
**Reason on** Annual Report  
Description: Request Acceptance and Approval of Annual Report covering July 21, 2018 - July 20, 2019 period
20. NNR-11.323 PI: Lewis, Johnnye L. Ph.D.  
**Navajo Birth Cohort Study (NBCS)**  
**Reason on** Annual Report  
Description: Request Review and Acceptance of Annual Report covering August 23, 2018 - August 22, 2019 period  
**Reason on** Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering May 23 - August 22, 2019 period
21. NNR-06.182 PI: Wallerstein, Nina Dr.PH  
**Listening to Each Other Curriculum Development Research Project**  
**Reason on** Annual Report  
Description: Request Acceptance and Approval of Annual Report covering October 21, 2018 - October 21, 2019 period  
**Reason on** Continuation Request  
Description: Request Acceptance and Approval of Continuation Request covering October 21, 2019 - October 21, 2020 period

22. NNR-02.094 PI: Knowler, William MD

**Action for Health in Diabetes Look AHEAD**

**Reason on** Amendment

Description: Request Review and Acceptance of 4 Amendments and Consent Forms: 1-Changed headers to reflect Version 21 and date, 2-Changes Footers to Reflect version 21 and Date, 3- Page 3 added twenty-first revision, 4- page 40 removed fasting from the statistical analysis plan participants have the option for doing a non-fasting visit.

23. NNR-11.342 PI: O'Connell, Joan M. Ph.D.

**Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using Enhanced Data**

**Reason on** Approval for Dissemination

Description: Request Acceptance and Approval Power Point Presentation from Published Manuscripts

24. NNR-13.160 PI: Greyeyes, Wendy Ph.D.

**The Dependency of Sovereignty**

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Reports covering 1) August 19, 2008 - August 20, 2019, 2) August 19, 2017 - August 20, 2018 periods.

**Reason on** Addendum

Description: Request Review and Acceptance of Letter of Hardship

**Reason on** Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering 1) August 19, 2018 - August 20, 2019, 2) August 19, 2017 - August 20, 2018 periods

25. NNR-15.224 PI: Watanabe, Kohei

**Ethnography of Laughter: Laughter of Dine and Creation of Hozo**

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 20, 2018 - October 20, 2019 period

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering January 20, 2019 - April 19, 2019, and April 20 - July 19, 2019 period

**Reason on** Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 20, 2019 - October 20, 2020 period

26. NNR-16.245 PI: Gittelsohn, Joel Ph.D

**Engaging Tribal Policy Makers to Sustain Improvements to the Food and Physical Activity in American Indian Communities (OPREVENT2)**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June - August 2019 period

**Reason on** Conference Presentation

Description: Request Review and Acceptance of Conference Presentation of Abstract Titled: Gestational diabetes among Native American women: Lifetime prevalence and risk Factors based on the OPREVENT2 Study at American Public Health Association's Annual Meeting on November 29, 2019 in Philadelphia, PA.

27. NNR-16.251 PI: Frank, Daniel MS **TABLED – used item from August 20<sup>th</sup> Meeting packet**

**Investigating Culturally-Contextualized Making with the Navajo Nation**

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 19, 2018 - July 19, 2019 period

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 20, 2019 - July 19, 2019

**Reason on** Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering July 19, 2019 - July 19, 2020 period

28. NNR-16.263 PI: Harris, Robin B. PhD., MPH

**Helicobacter Pylori Infection and Stomach Cancer**

**Reason on** Amendment

Description: Request Acceptance and Approval of Amendments; Sample individual household results with explanation of results and Strategies to reduce arsenic water intake if necessary, and slide of summary results that can be inserted into the chapter and agency and community presentations,

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 31 - August 31, 2019 period

29. NNR-17.276 PI: Keene, Chesleigh N MA, BA **TABLED – used item from September 17 Meeting packet**

**Help-seeking attitudes and behaviors: Factors in influencing differences among urban versus reservation-dwelling native**

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 18, 2017 - July 18, 2018 period. Attachments Study Abstract and Summary.

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: July 18, 2017 - October 18, 2017; October 18, 2017 - January 18, 2018; January 18, 2018 - April 18, 2018; April 18, 2018 - July 18, 2018; July 18, 2018 - October 18, 2018; October 18, 2018 - January 18, 2019; January 18, 2019 - April 18, 2019; April 18, 2019 - July 18, 2019 periods.

30. NNR-17.281 PI: Garrison, Nanibaa' Ph.D.

**Perspetives on Genetic Research in the Navajo Nation**

**Reason on** Amendment

Description: Request Acceptance and Approval of Amendment 1- to remove the following Study Personnel: Christie Kelly, Donovan Carr, Dr. Johynne Lewis; 2- Addition of an aim: Literature Review on Genetic Research with the Navajo.

**Reason on** Conference Presentation

Description: Request Acceptance and Approval of updated presentation slides for presentation at Navajo Research Conference on October 16-17, 2019 in Window Rock, AZ and Society for the Advancement of Chicanos and Native Americans in Science Conference in Honolulu, Hawaii on October 31 - November 2, 2019

31. NNR-17.286 PI: Whyte, Ayn N. MS

**American Indian/Alaska Native Health Equity Initiative**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) February - April 2019, 2) May - July 2019 periods

**Reason on** Annual Report

Description: Request Acceptance and Approval of Draft Annual Report covering November 29, 2018 - November 29-2019 period

**Reason on** Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering November 29, 2019 - November 29, 2020 period

32. NNR-17.289 PI: Nawrocki, Rachel B.S.

**Youth Builders**

**Reason on** Addendum - **TABLED – used item from September 17 Meeting packet**

Description: Request Acceptance and Approval of Report document use for report to Department of Din'e Education, Navajo Department of Health, Navajo Head Start, and School Boards.

**Reason on** Approval for Dissemination

Description: Request Acceptance and Approval of Power Point Presentation for Navajo Department of Health on October 15, 2019.

33. NNR-02.110 PI: Knowler, William MD

**Diabetes Prevention Program Outcomes Study (DPPOS)**

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 19, 2018 - August 19, 2019 period

34. NNR-18.298 PI: Van Horne, Yoshire Ornelas  
**Exposures and Health Risks to the Din'e communities impacted by the Gold King Mine Spill**  
**Reason on** Conference Presentation  
**Description:** Request Acceptance and Approval of Conference Presentation Abstract Titled: Exposures and Health Risks of the Dine' Communities Impacted by the Gold King Mine Spill on October 23, 2019 in Tucson, AZ at American Indian Health Disparities Course at Dine' College.
35. NNR-18.330 PI: Hudson, Laurie G PhD  
**Thinking Zinc**  
**Reason on** Amendment  
**Description:** Request Acceptance and Approval of Amendment to utilize different Instrument: A 24 hour food recall survey
36. NNR-18.307 PI: Hammitt, Laura M.D.  
**Safety and Immunogenicity of V114 in Adults at Risk for Pneumococcal Disease (Adult PCV15 Study)**  
**Reason on** Addendum  
**Description:** Request Acceptance and Approval of Regulatory documents: Updated Investigator Brochure dated 9-11-19 and 15 Day non Clinical Safety Report dated 9-20-19.
37. NNR-19.357 PI: Hammitt, Laura M.D.  
**A Phase 3 Randomized, Double, Placebo-controlled Study to evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody with an Extended Half-Life Against respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)**  
**Reason on** Amendment  
**Description:** Request Acceptance and Approval of Amendments: 1) Revised Contact Form, 2) Revised Case Report Forms, 3) Revised Inclusion - Exclusion Checklist, 4) Revised Randomization Verification Form, 5) Revised Medical History Form, 6) New Physical Exam Form.
38. NNR-19.350 PI: Hammitt, Laura MD  
**Surveillance for RSV and Other Respiratory Infections among Native American Children and Pregnant Women**  
**Reason on** Amendment  
**Description:** Request Acceptance and Approval of Amendments: 1- Revised Chart Review and Questionnaires for Child and Pregnant Woman; 2- New Participants letters for Children and Pregnant Women.
39. NNR-15.199 PI: Shin, Sonya MD  
**REACH for Healthy Navajo Communities.**  
**Reason on** Conference Presentation  
**Description:** Request Acceptance and Approval of Power Point Presentation for Conference Presentation at Sweet Success 23rd Annual National Research Conference on November 7-9, 2019 in Anaheim, CA.

- IX. Noon Hour Discussion: *2019 Navajo Research Conference: Pre-Conference Session Agenda, Two Day Conference Agenda*
- X. Abstracts Review: Gay Navajo Description f Settle Colonial Leadership: A Descriptive Study – *Andy Nez, Grand Canyon University*
- XI. Announcement / Adjournment: